

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Appln. No. 09/236,897
Attorney Docket No.: Q53086

REMARKS

Claims 1, 2, 4-6, and 8-33 are all the claims pending in the Application. By this Amendment, Applicant amends claims 1, 5, 9, 16, and 21-23. In addition, Applicant adds claims 24 to 33. Claims 24 through 33 are clearly supported throughout the specification, *e.g.*, Fig. 1, page 22 of the specification.

Preliminary Matters

The Examiner retained previous rejections alleging that Applicant's arguments submitted in the Amendment under 37 C.F.R. § 1.111 filed November 26, 2003 are unpersuasive. In particular, the Examiner rejected claims 1, 2, 5-6, and 9-20 under §103(a) as being unpatentable over US Patent No. 4,296,069 to Smith et al. (hereinafter Smith) in view of US Patent No. 6,180,061 to Bogen et al. (hereinafter Bogen) and US Patent No. 5,059,393 to Quenin et al. (hereinafter Quenin). In addition, the Examiner rejected previously added claims 21-23 under 35 U.S.C. § 103(a) as being unpatentable over Smith in view of Bogen and Quenin. Finally, claims 4 and 8 stand rejected under 103(a) as being unpatentable over Smith in view of Bogen and Quenin and further in view of US Patent No. 5,814,277 to Bell et al. (hereinafter Bell). These rejections are respectfully traversed in view of the following remarks.

To begin, arguments submitted in the Amendment under 37 C.F.R. § 1.111 filed on November 26, 2003 are respectfully incorporated herein by reference. Moreover, additional comments are presented below with respect to each of these rejections.

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Obviousness in view of Smith, Bogen and Quenin

Claims 1, 2, 5, 6, and 9-23 stand rejected as being unpatentable over Smith in view of Bogen and Quenin. Of these claims, only claims 1, 5, 9, and 16, are independent. This response will initially focus on the independent claims 1, 5, 9 and 16.

In the rejection of the system claims 1, 5, 9, and 16, under 35 U.S.C. § 103(a), the Examiner maintains that Bogen teaches an incubator capable of holding the slides at different temperatures, Quenin teaches a bar code reader, and Smith teaches all other limitations of the independent claims 1, 5, 9, and 16. Moreover, the Examiner asserts that combining the three references would have been obvious to allow for more efficient operation (pages 3-4 and 5-7 of the Office Action). This ground of rejection is respectfully submitted to be incorrect as a technical matter.

The initial burden of establishing that a claimed invention is *prima facie* obvious rests on the USPTO. *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To make its *prima facie* case of obviousness, the USPTO must satisfy three requirements:

- a) the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated to artisan to modify a reference or to combine references. *In re Thrif*, 298 F.3d 1357, 1363 (Fed. Cir. 2002).
- b) the proposed modification of the prior art must have had a reasonable expectation of success, and that determined from the vantage point of the artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991).
- c) the prior art reference or combination of references must teach or suggest all the limitations of the claims. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

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The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, the nature of a problem to be solved. *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). Alternatively, the motivation may be implicit from the prior art as a whole, rather than expressly stated. *Id.* Regardless if the USPTO relies on an express or an implicit showing of motivation, the USPTO is obligated to provide particular findings related to its conclusion, and those findings must be clear and particular. *Id.* A broad conclusionary statement, standing alone without support, is not “evidence.” *Id.*; see also, *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

In addition, a rejection cannot be predicated on the mere identification of individual components of claimed limitations. *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Rather, particular findings must be made *as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed*, emphasis added. *Id.*

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See *In re Kotzab*, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (*citing In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)). Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the

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invention taught is used against its teacher.” *Kotzab*, 55 USPQ2d at 1316 (*quoting W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

Most if not all inventions arise from a combination of old elements, emphasis added.

In re Kotzab, 55 USPQ2d at 1316 (*citing In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998)). Thus, every element of a claimed invention may often be found in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *Id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab*, 55 USPQ2d at 1316 (*citing In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); and *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

There is no motivation to combine the references in a manner suggested by the Examiner. In response to Applicant’s arguments that there is no motivation to combine the references, the Examiner alleges that motivation was provided for each of the modifications to the Smith reference and that no knowledge gleaned only from the Applicant’s disclosure has been used (see page 7 of the Office Action).

For example, the Examiner alleges that one of ordinary skill in the art would have opted for the Quenin’s bar code reader over Smith’s optical source because of the ability of the bar code reader to obtain additional information such as a slide type. Smith’s system, however, focuses on a slide transfer mechanism, which is operable to selectively remove a slide from an

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incubator and transfers the slide to a read station for measuring a characteristic of a sample fluid. The slide is either returned to the incubator by the slide transfer mechanism for later analysis or is discarded by the slide transfer mechanism following analysis (col. 2, lines 5 to 17).

To facilitate the transfer of slides, Smith teaches an optical sensing mechanism 120, which detects the leading edge of a slot in the disk 115 plus one additional step. This places the middle of the slot at the sensor and a slide-supporting station of the rotor 44 at the desired position after each advancement of the rotor 44 (Fig. 5; col. 5, lines 26 to 62) so as to move one station out of the transfer location 45 and the next station into the transfer location. This arrangement facilitates the precise positioning of slides 15 in the individual stations on rotor 44 relative to the input position 43 and the transfer location 45. In short, optical sensing mechanism 120 is used for detecting the leading edge of the slot. Another optical sensor mentioned by Smith is for a disposal station 190. In particular, Smith teaches an optical sensor (not shown) may be included to sense the operative position of the diverter (Fig. 6, col. 7, lines 7 to 25). In short, Smith teaches one optical sensor detects the leading edge of the slot and another one detects the operational state of the discarding mechanism.

Quenin, on the other hand, mentions in passing that the kind of slide that is being supplied to the fluid dispensing station is best determined by a bar code reader (not shown) that reads bar code labels on the slides as they move towards the fluid dispensing station, as is well known in the art (col. 4, lines 32 to 36). Since Smith, however, uses sensors for sensing mechanical movements of the elements (detecting positioning of mechanisms), replacing the sensors with a bar code reader makes little sense. That is, there is no suggestion or motivation to

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include a bar code reading for a transfer mechanism because the transfer mechanism does not have a type or other information that needs to be read. In other words, to detect movement, sensors are considered more efficient and are usually used as opposed to the bar code readers. In short, from these two references, there is no motivation or suggestion to replace the Smith's optical source with the bar code reader of Quenin in a manner suggested by the Examiner.

For at least this exemplary reason, it is respectfully submitted that there is no motivation to combine Smith and Quenin in the manner suggested by the Examiner. Therefore, the Examiner cannot fulfill the "motivational" prong of a *prima facie* case of obviousness, as required by *In re Thrif*.

In addition, independent claims 1, 5 and 16 recite a number of unique features not found in the prior art references cited by the Examiner. For example, independent claim 1 recites: *a temperature control means for automatically holding the first chemical analysis element at a first predetermined temperature for measuring the optical density and the second chemical analysis element at a second predetermined temperature suitable for measuring ionic activity*. From hereinafter, this recitation will be referred to as "control means for holding different types of slides at different temperatures" for the sake of linguistic convenience only.

The Examiner acknowledges that Smith and Quenin fail to teach such control means. The Examiner, however, alleges that Bogen cures the deficient teachings of Smith and Quenin (page 3 of the Office Action). In particular, in response to arguments in the Amendment filed on November 26, 2003, the Examiner alleges that "the claims do not invoke 112, 6th paragraph" and that "one of ordinary skill in the art would have believed that with the incubator of Bogen would

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have been capable of maintaining different temperatures for different slides” (see page 6 of the Office Action).

In response, it is respectfully pointed out that original claims 1, 5 and 16 recite “temperature control means which holds...”. MPEP § 2181 sets out a three prong test for a claim limitation to be interpreted to invoke 35 U.S.C. § 112, sixth paragraph: (a) the claim limitations must use the phrase “means for” or “step for”; (b) the “means for” or “step for” must be modified by functional language, and (c) the phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function.

With respect to the first prong, it can be met “even though the phrase “means for” or “step for” is not used, [if] a *claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts* which would preclude application of 35 U.S.C. § 112, sixth paragraph, (emphasis added), *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000). The limitation at issue in claims 5 and 16 recites the term “means” and as acknowledged by the Examiner, the limitation recites a “function”. Therefore, it is respectfully submitted that the limitation at issue in claims 1, 5 and 16 can be distinguished based on function.

For the sake of expediting prosecution, however, claims 1, 5 and 16 are editorially amended to recite “means for”. The amendments to claims 1, 5 and 16, as explained above, were made for reasons of precision of language and consistency, and do not narrow the literal scope of the claims and thus do not implicate an estoppel in the application of the doctrine of equivalents. The amendments to claims 1, 5 and 16 were not made for reasons of patentability.

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Next, the Examiner alleges that “one of ordinary skill in the art would have believed that with the incubator of Bogen would have been ‘capable of maintaining different temperatures for slides’” (page 6 of the Office Action). First, it is respectfully pointed out that what one of ordinary skill in the art would have believed is not the proper standard for establishing obviousness but rather the proper standard is what the reference teaches to one of ordinary skill in the art.

In addition, it is respectfully pointed out that the Examiner failed to show that Bogen teaches a suitable temperature for measuring ionic activity and a suitable temperature for measuring the optical density of the color formed by the chemical analysis. Bogen clearly fails to teach or suggest holding these types of temperatures.

Furthermore, the Examiner alleges that “each heating element has its own electrical power connection and an electrical control and individual temperature sensor” (see page 6 of the Office Action). It is respectfully pointed out that this is incorrect as a technical matter. For example, Bogen teaches one electronic control for all the heating elements (e.g. claim 1). In particular, Bogen teaches a microprocessor, which controls the entire dispensing assembly 500. That is, an operator programs the microprocessor with the information such as the location of reagents on the reagent rotor and the location of slides on the slide rotor. The operator then programs the particular histochemical protocol to be performed on the tissue samples. Variables in these protocols can include the particular reagent used on the tissue sample, the time that the tissue sample is allowed to react with the reagent, whether the tissue sample is then heated to expose or develop the tissue sample, the rinse that is then used to deactivate the reagent,

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followed by the subsequent removal of the rinse and the reagent to allow subsequent exposure to a possibly different reagent. The dispensing assembly enables complete random access, *i.e.*, any reagent to any slide in any sequence (col. 8, lines 16 to 30).

Bogen, however, teaches that the operator must manually enter all the information into the microprocessor including whether the element is to be heated. Bogen's system cannot recognize the type of slide and based on the type of slide, hold it at a certain temperature. In Bogen, all the information is manually entered by the operator. Moreover, the operator sets the temperature to which a slide is to be heated. Therefore, Bogen does not teach or suggest automatically holding different slides at different temperatures. At which temperatures the slides are being held is simply not taught by Bogen (two different types of slides may be heated to the same temperature).

To sum up, Bogen does not teach or suggest holding the slides at a temperature for measuring ionic activity and another slide at a temperature suitable for measuring the optical density. In addition, Bogen fails to teach or suggest holding the slides based on the slide type, instead the slides are heated up based on user input.

In short, neither of the references, either alone or in combination, teaches or suggests *a temperature control means for automatically holding the first chemical analysis element at a first predetermined temperature for measuring the optical density and the second chemical analysis element at a second predetermined temperature suitable for measuring ionic activity*, as set forth in claims 1 and 5 and *a temperature control means for holding the first chemical analysis element at a first predetermined temperature for measuring the optical density and the*

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second chemical analysis element at a second predetermined temperature suitable for measuring ionic activity, as set forth in claim 16. Thus, it is respectfully submitted that with respect to claims 1, 5, and 16, the Examiner cannot fulfill the “all limitations” prong of a *prima facie* case of obviousness, as required by *In re Vaeck*.

Next, this rejection is traversed with respect to independent claim 9, which among a number of unique features not taught by references cited by the Examiner, as now amended, recites: *a bar code reader to detect the position of the chemical analysis element and a temperature control device comprising a temperature control element and a first pressing member for the first chemical analysis element and a second pressing member for the second chemical analysis element, the temperature control device holds the first and second chemical analysis elements at predetermined temperatures.*

The Examiner alleges that since the bar code reader of Quenin detects the type of slide as the slides move towards the fluid dispensing station, Quenin’s bar code reader would obviously be able to track the slide on its way to the fluid dispenser (see page 7 of the Office Action). It is respectfully pointed out, however, that Quenin does not teach or suggest using a bar code to detect a location. In fact, Quenin, similar to Smith uses sensors for detecting positional elements (e.g., for the transfer mechanism), col. 5, lines 25 to 31. In short, it is respectfully pointed out that Quenin does not teach or suggest detecting positional aspects using a bar code reader.

Moreover, neither Smith, Quenin, or Bogen, taken alone or in any conceivable combination teach a control device comprising a control element and two pressing members (one for each type of slide), as set forth in claim 9.

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For at least the above-noted exemplary reasons, independent claims 1, 5, 9, and 16 are patentable over Smith in view of Bogen and Quenin. Accordingly, it is appropriate and necessary for the Examiner to withdraw this rejection of independent claims 1, 5, 9, and 16. Finally, claims 2, 6, 10-15, and 17-20, are patentable at least by virtue of their dependency on the independent claims 1, 5, 9, and 16.

Obviousness in view of Smith, Bogen, Quenin and Bell

Claims 4 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith, Bogen, and Quenin, in view of Bell. The Examiner's careful reconsideration is respectfully requested in view of the following comments traversing the rejection. As set forth above, Smith, Bogen and Quenin do not teach or suggest all the elements as set forth in independent claims 1, 5, 9, and 16. Bell is relied upon only for its teaching of automated dilution. Clearly, Bell does not compensate for the above-identified deficiencies of Smith, Bogen, and Quenin. Together, the combined teachings of these references would not have (and could not have) led one of ordinary skill in the art to have achieved the subject matter of claims 1 and 5. Since claims 4 and 8 are dependent upon claims 1 and 5, respectively, they are patentable at least by virtue of their dependency.

New Claims

Finally, in order to provide more varied protection and to further distinguish the prior art cited by the Examiner, Applicant adds claims 24-33. Claim 24 is patentable at least by virtue of its dependency on claim 9. Moreover, Applicant respectfully submits that the combined teachings of Smith, Bogen, Quenin, and Bell do not teach or suggest having the pressing

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members of different shapes for different types of slides to maintain different temperatures. For at least this additional reason, Applicant respectfully submits that claim 24 is patentable over the combined teachings of Smith, Bogen, Quenin, and Bell.

Of the remaining added claims, only claims 25 and 30 are independent. Claim 25 recites “a first measuring means for measuring the first chemical property of the first chemical analysis element, the first measuring means being provided in the incubator...a second measuring means for measuring the second chemical property of the second chemical analysis element, the second measuring means being provided in the incubator,” and claim 30 recites “a concentration measuring means for measuring the concentration of the specific component contained in the sample liquid on the first chemical analysis element, which is provided in the incubator, by measuring the optical density of color formed by a coloring reaction of the sample liquid and a reagent on the first chemical analysis element...an ionic activity measuring means for measuring the ionic activity of the specific ion contained in the sample liquid on the second chemical analysis element, which is provided in the incubator.”

The combined teachings of Smith, Bogen, Quenin, and Bell, taken alone or in any conceivable combination fail to teach or suggest performing measurements in the incubator for the first and second chemical analysis elements. In these references, as in the conventional techniques, the analysis elements are taken out of the incubator to perform measurements. In short, the combined teachings of these references fail to teach or suggest measuring the chemical property of the first and second chemical elements in the incubator. For at least these exemplary reasons, Applicant respectfully submit that independent claims 25 and 30 are patentable over the

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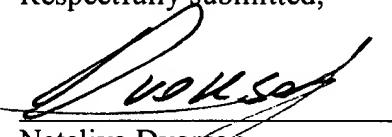
prior art references cited by the Examiner. In addition, Applicant respectfully submits that claims 26-29 and 31-33 are patentable at least by virtue of their dependency on claim 25 and 30, respectively.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly invited to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. **Please note that the Excess Claim Fee was already paid on September 20, 2004. The Request for Refund filed on March 2, 2005 is only for the RCE statutory fee.**

Respectfully submitted,


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